

Atty Dkt. No.: SIER-022CON
USSN: 10/826,466RECEIVED
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REMARKS***Formal Matters***

Claim 46 has been amended to include the following elements: 1) contacting the agent with a second expression system containing a second coding sequence operably linked to a TERT promoter that is not operatively linked to a GC-Box5 repressor binding element (see step (b) of the amended claim); and 2) identifying the agent as an agent that inhibits GC-Box 5 repression of TERT transcription if transcription of the first coding sequence (i.e., the one containing the GC-Box5 element) is not repressed in the presence of the agent and transcription of the second coding sequence (i.e., the one lacking the GC-Box5 element) is not altered. Expression systems for use in screening assays as described in element (b) of amended Claim 46 are found in the specification (e.g., paragraphs [76], [77] and [[91]]), these amendments are fully supported by the specification.

Claims 48, 55, 56 and 59 have been amended to be consistent with the amendments to Claim 46.

As no new matter is added by way of these amendments, entry thereof by the Examiner is respectfully requested.

Interview Summary

A telephonic interview was held with the Examiner (Marcia Noble) and her supervisor (Joseph Woitach) on October 3, 2006, to discuss the outstanding 35 USC §112 rejection. In this interview it was stated that the outstanding §112 rejection would be overcome if the only independent claim (Claim 46) made clear the nexus between the GC-Box5 element and the activity of the agent on TERT transcription from the expression system.

As is discussed below, the Applicants have amended Claim 46 as suggested by the Examiner.

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Double Patenting

In the Advisory Action of August 16, 2006, the Examiner stated that the Terminal Disclaimer filed in response to the Final Office Action has overcome the Double Patenting rejection.

Claim Rejections – 35 USC § 112

In the Advisory Action of August 16, 2006, the Examiner maintained the rejection of Claims 46, 48, 49 and 53 – 61 under 35 USC § 112, first paragraph for failing to comply with the enablement requirement.

As currently amended, Claim 48 of the present invention is drawn to a method of determining whether an agent inhibits GC-Box 5 repression of TERT transcription. This method includes the steps of (underline indicates relevant amendments): (a) contacting the agent with a first expression system containing a GC-Box 5 repressor binding site and a first coding sequence operably linked to a TERT promoter under conditions such that in the absence of the agent transcription of said coding sequence is repressed; (b) contacting the agent with a second expression system comprising a second coding sequence operably linked to a TERT promoter that is not operatively linked to a GC-Box5 repressor binding element; (c) determining whether transcription of the coding sequence is repressed in the presence of the agent; and (d) identifying the agent as an agent that inhibits GC-Box 5 repression of TERT transcription if transcription of the first coding sequence is not repressed in the presence of the agent and transcription of the second coding sequence is not altered.

In maintaining this rejection, the Examiner asserts that a nexus between the GC-Box5 regulatory element and the activity of the agent has not been established.

As noted in the *Interview Summary* section above, the Examiner stated that the §112 enablement rejection would be overcome if the only independent claim (Claim 46) made clear the nexus between the GC-Box5 element and the activity of the agent on TERT transcription from the expression system.

As indicated above, the Applicants have amended Claim 46 such that an agent is identified as an agent that inhibits GC-Box 5 repression of TERT transcription if

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transcription from a first expression system (i.e., one comprising a GC-Box 5 repressor binding site and a coding sequence operably linked to a TERT promoter) is not repressed in the presence of the candidate agent and the agent does not affect TERT transcription when contacted to a second expression system comprising a TERT promoter that is not operably linked to a GC-box 5 repressor binding site. These amendments make clear that for an agent to be identified as one that inhibits GC-Box 5 repression of TERT transcription, it can not affect transcription from an expression system that does not contain a GC-Box5 binding site. In this way, the nexus between the GC-Box5 element and the activity of the agent is clear.

In view of these amendments, the Applicants submit that they have complied with the requirements set forth by the Examiner in the interview of October 3, 2006, and as such respectfully request withdrawal of this rejection.

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CONCLUSION

In view of the amendments and remarks above, the Applicants respectfully submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Bret Field at (650) 833-7770.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, order number SIER-022CON.

Respectfully submitted,
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